

K/006/6
163

510 (k) Summary

MAY 20 2010

Life Technologies Corporation - Knockout™ SR Medium and Knockout™ SR Xenofree Medium

Device Name: Knockout™ SR Medium
Knockout™ SR Xenofree Medium

Common/Usual Name: KSR
KSR Xenofree

Classification Name: Tissue culture media for human *ex vivo* tissue and cell culture processing applications (per 21 CFR § 876.5885)

Product Code: NDS

Submitter: Life Technologies Corporation
3175 Staley Road
Grand Island, New York 14072

Telephone: (716) 774-3122

Facsimile: (716) 774-0230

Email: kelli.tanzella@lifetech.com

Contact: Kelli Tanzella, Ph.D.

Date Prepared: March 01, 2010

Predicate Device:

<u>Trade Name</u>	<u>Manufacturer</u>	<u>510(k)</u>
AIM-V® Medium	Life Technologies Corporation (formerly Invitrogen Corporation)	K022086

Intended Use

Knockout™ SR Medium and Knockout™ SR Xenofree Medium are liquid tissue culture media product intended for human *ex vivo* tissue and cell culture processing applications.

Substantial Equivalence

AIM-V® Medium is the predicate device for tissue culture media intended for human *ex vivo* tissue and cell culture processing applications. It is composed of chemically defined nutrient materials in solution (with or without supplements) that are essential for the survival and development of tissue or cells of human or other animal origin. These nutrients are provided in liquid form for use in supporting the growth or maintenance of human tissue and cells.

A. Intended Uses

Knockout™ SR Medium and Knockout™ SR Xenofree Medium and AIM-V® Medium tissue culture products are intended for human *ex vivo* tissue and cell culture processing applications. These devices are chemically defined tissue culture media used to support the growth or maintenance of human tissue or cells in culture.

B. Principles of Operation and Technological Characteristics**Knockout™ SR**

Knockout™ SR is a serum-free medium with a defined formulation that provides consistent growth conditions for human and mouse embryonic stem cell (ESC) and patient-specific induced pluripotent cell lines (iPSCs). Both ESC and iPSC grown in Knockout™ SR supplemented media are substantially less differentiated than those grown in fetal bovine serum (FBS) supplemented media. This media was introduced in 1998 and there are over 300 literature references to Knockout™ SR.

Knockout™ SR Xenofree

Knockout™ SR Xenofree is a serum-free and animal origin-free defined formulation that provides consistent growth conditions for human and mouse embryonic stem cell (ESC) and patient-specific induced pluripotent cell lines (iPSCs). All animal derived components have been replaced with human derived or synthetic components to yield a xenogeneic-free formulation. This media was developed and marketed in 2008.

C. Pre-clinical Testing**Performance Standards**

Performance standards under Section 514 of the Federal Food, Drug, and Cosmetic Act have been established in Guidance Document "Class II Special Controls Guidance Document: Tissue Culture Media for Human *Ex Vivo* Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers," issued May 16, 2001. The specific assay tests and Life Technologies Corporation's equivalent tests that were conducted are identified in the table below.

Special Control Objective	Life Technologies Corporation Knockout™ SR Medium
Demonstrate lack of potential toxicity of materials in the media to cells or tissue and demonstrate support of tissue and cell growth	ES Cell Morphology, relative plate efficiency, and relative type 1 colonies
Demonstrate lack of endotoxin or pyrogen contamination	Limulus Amebocyte (LAL) test (25 USP Monograph <85>)
Validation of Aseptic Processing and Sterility Assurance Level (SAL)	Determination of SAL to be $\geq 10^{-3}$ compliance with GMP requirements regarding aseptic processing
Demonstrates Chemical purity	Incoming Raw Material testing using USP, ACS, FCC, GIBCO, or Cell Culture requirements.

Stability/Shelf Life

Based on analysis of product performance over time, Life Technologies Corporation has established a shelf life of 14-months for Knockout™ SR Medium and Knockout™ SR Xenofree Medium formulations, when stored between 2°C-8°C. Stability testing involved the assessment of these functional aspects of media, including demonstrating: (1) that the pH continued to meet specifications; and (2) the media was not cytotoxic and supported the growth of mammalian cells. The pH was tested to demonstrate that the media was not chemically altered during its storage. In assessing cytotoxicity/biocompatibility, Life Technologies Corporation demonstrated that the media functions in supporting the growth of mammalian cells and that the media does not become toxic to mammalian cells during storage. In addition, results from container/closure integrity testing have demonstrated that the container/closure system provides protection from microbial contamination.

D. Conclusion

Knockout™ SR Medium and Knockout™ SR Xenofree Medium and AIM-V® Medium are used for human *ex vivo* tissue and cell culture processing applications and have the same principles of operation, technological characteristics, efficacy (generic cellular growth and maintenance) and safety (consistency in chemical content and formulation, biocompatibility with cells, and purity). Their efficacy in supporting the survival, growth, development, and maintenance of human cells or tissue culture systems has been well established in scientific publications included in this submission. These products (Knockout™ SR Medium and Knockout™ SR Xenofree Medium and AIM-V® Medium) are manufacturer in accordance with QSR requirements and are labeled as aseptically processed. Thus, Knockout™ SR Medium and Knockout™ SR Xenofree Medium are substantially equivalent to the legally marketed device intended for the human *ex vivo* tissue and cell culture processing applications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Kelli L. Tanzella, Ph.D.
Senior Manager, Americas Regulatory Affairs
Life Technologies
3175 Staley Road
GRAND ISLAND NY 14072

MAY 20 2010

Re: K100616
Trade/Device Name: Knockout™ SR Medium
Knockout™ SR Xenofree Medium
Regulation Number: 21 CFR §876.5885
Regulation Name: Tissue culture media for human ex vivo tissue and cell culture
processing applications
Regulatory Class: II
Product Code: NDS
Dated: March 4, 2010
Received: March 4, 2010

Dear Dr. Tanzella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

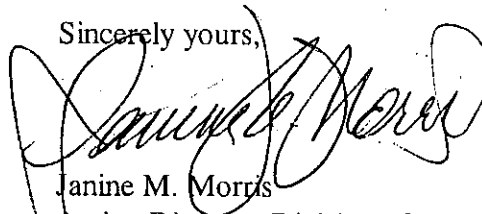
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

K100616

Device Name: Knockout™ SR Medium
Knockout™ SR Xenofree Medium

Indications for Use:

Knockout™ SR Medium and Knockout™ SR Xenofree Medium are liquid tissue culture medium products intended for human *ex vivo* tissue and cell culture processing applications.


(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒
(Optional Format 1-2-96)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K100616